UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

DANIELLE BAKSIC and BRIAN BAKSIC, Plaintiffs, v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	CASE No.: 5:20-cv-00920 COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL 1. Strict Liability – Failure to Warn 2. Strict Liability – Design Defect 3. Negligence 4. Loss of Consortium

PLAINTIFFS' ORIGINAL COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, Plaintiffs Danielle Baksic and Brian Baksic, and files their Original Complaint in the above-styled cause of action complaining of Defendants Ethicon, Inc. and Johnson & Johnson, and would respectfully show the Court as follows:

I. PARTIES AND SERVICE

1. Plaintiffs Danielle Baksic and Brian Baksic are individual citizens residing in Ewa Beach, Honolulu County, Hawaii.

2. Defendant Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson with its corporate headquarters in Somerville, New Jersey. Defendant Ethicon is a foreign corporation licensed to do business in the State of Texas and may be served by serving its registered agent, C T Corporation System, at 1999 Bryan Street, Ste. 900, Dallas, Texas 75201.

3. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation that has its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, Middlesex

County, New Jersey. Defendant Johnson & Johnson does business in the State of Texas but does not maintain a registered agent for service of process in this state. Therefore, Johnson & Johnson may be served with process by serving the Texas Secretary of State as substituted agent for service of process under Tex. Civ. Prac. & Rem. Code §§ 17.044(a) and (b) at the following address: Office of the Secretary of State, Statutory Documents Section-Citations Unit, 1019 Brazos Street, Austin, Texas 78701.

II. JURISDICTION & VENUE

4. Plaintiffs Danielle Baksic and Brian Baksic were residents of the Western District of Texas at the time of Plaintiff Danielle Baksic's implant of the Ethicon device, which surgery occurred at Baptist Health Medical Center in San Antonio, Texas.

5. Defendant Johnson & Johnson and its wholly owned subsidiary, Defendant Ethicon, Inc., are foreign corporations with their principal places of business in a state other than the State of Texas.

6. The Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332. The amount in controversy as to each Defendant exceeds the sum of $75,000, exclusive of costs and interest, and the action is between citizens of different states.

7. Venue in this District is proper under 28 U.S.C. § 1391. The events and omissions giving rise to Plaintiffs' causes of action occurred in substantial part in this District, where the Defendants transact business and where a substantial part of the events or omissions giving rise to this claim occurred.

III. FACTUAL BACKGROUND

The Pelvic Mesh Products

8. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging,

labeling, and selling such devices, including the GYNECARE TVT™ Obturator System, ("Pelvic Mesh Product"). The Pelvic Mesh Product is a product targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of weakening or damage to the walls of the vagina. The Pelvic Mesh Product is represented by Defendants to correct and restore normal vaginal structure by implantation of polypropylene mesh in the vaginal wall tethered in place by two arms that extend up through the buttocks. It is specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting stress urinary incontinence.

9. Prior the implantation of the Pelvic Mesh Product at issue in this claim, Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Pelvic Mesh Product under Section 51O(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 51O(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

10. Despite claims that the monofilament polypropylene mesh in the Pelvic Mesh Product is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

11. The Pelvic Mesh Product has been and continues to be marketed to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

12. Defendants marketed and sold the Pelvic Mesh Product through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of this product.

13. Contrary to the representations and marketing of Defendants, the Pelvic Mesh Product has high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating revision surgeries, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Danielle Baksic. The defects stem from many issues, including:

a. the use of polypropylene material in the Pelvic Mesh Product and the immune reaction that results;

b. the design of the Pelvic Mesh Product to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction or shrinkage of the mesh;

d. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade;

e. the use and design of anchors in the Pelvic Mesh Product that when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

f. degradation of the mesh itself over time which causes the internal tissue to degrade;

g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

h. the design of the trocars (devices used to insert the Pelvic Mesh Product into the vagina) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

14. Upon information and belief, Defendants have consistently underreported and withheld information about the propensity of their Pelvic Mesh Product to fail and cause injury and complications, and have misrepresented the efficacy and safety of this product, through various means and media, actively and intentionally misleading the public.

15. Despite the chronic underreporting of adverse events associated with the Pelvic Mesh Product, enough complaints were recorded for the Food and Drug Administration ("FDA") to issue a public health notification regarding the dangers of this device.

16. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the Pelvic Mesh Product and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendants are some of the manufacturers of the products that are the subject of the notification.

17. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded

that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of **"continuing serious concern"** (emphasis added). The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh-kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendants and was not disclosed in any manner.

18. Defendants have further known the following:

a. that some of the predicate devices for the Pelvic Mesh Product had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Pelvic

Mesh Product and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that the Pelvic Mesh Product was and is causing numerous patients severe injuries and complications.

19. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiffs. As a result, Defendants actively and intentionally misled and continue to mislead the public into believing that the Pelvic Mesh Product and the procedures for implantation were and are safe and effective.

20. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Product.

21. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Product; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Product.

22. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for repair of pelvic organ prolapse and stress urinary incontinence have existed at all times relevant to this matter.

23. The Pelvic Mesh Product was at all times utilized and implanted in a manner foreseeable to Defendants, as they generated the instructions for use, created the procedures for implanting the device, and trained the implanting physicians.

24. Defendants provided incomplete, insufficient, and misleading training and

information to physicians to increase the number of physicians utilizing the Pelvic Mesh Product, and thus increase the sales of this product.

25. The Pelvic Mesh Product implanted into Plaintiff Danielle Baksic was in the same or substantially similar condition as it was when it left the possession of Defendants, as well as being in the condition directed by and expected by these Defendants.

26. Plaintiff Danielle Baksic and her physician foreseeably used and implanted the Pelvic Mesh Product, and did not misuse or alter this product in an unforeseeable manner.

27. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Product include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

28. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Pelvic Mesh Product) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the device.

29. Defendants knew and had reason to know that the Pelvic Mesh Product could and

would cause severe and grievous personal injury to the users of the Pelvic Mesh Product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

30. At all relevant times herein, Defendants continued to promote the Pelvic Mesh Product as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

31. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiffs and the public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Product.

32. The Pelvic Mesh Product was defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

FACTS SPECIFIC TO PLAINTIFF DANIELLE BAKSIC

33. Upon information and belief, Bruce Akright, M.D. recommended the Pelvic Mesh Product to Plaintiff Danielle Baksic as appropriate and safe for the treatment of stress urinary incontinence. Consequently, Plaintiff consented to the implantation of the Pelvic Mesh Product.

34. On July 21, 2010, Plaintiff Danielle Baksic underwent surgery to address her stress urinary incontinence at Baptist Health Medical Center in San Antonio, Texas. During this surgery, she was implanted with an Ethicon Gynecare TVT-O sling (Catalog No. 810041B) by Dr. Bruce Akright, M.D.

35. On June 11, 2015, at Ronald Reagan UCLA Medical Center in Los Angeles, California, Plaintiff Danielle Baksic underwent surgery to remove the Gynecare TVT-O sling as it had eroded into surrounding tissue. Plaintiffs has continued to receive medical treatment since the date related to the eroded TVT-O sling.

36. As a result of having the Gynecare TVT-O sling implanted in her, Plaintiff Danielle Baksic has experienced significant mental and physical pain and suffering, to include dyspareunia, disabling pelvic pain, groin pain, leg pain, infections and difficulties walking, has sustained permanent injury and scarring, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

IV. DISCOVERY RULE, ESTOPPEL, AND FRAUDULENT CONCEALMENT

37. Plaintiffs incorporate by reference the factual portion of this complaint as if fully set forth herein and additionally, or in the alternative, if same be necessary, alleges as follows.

38. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

39. Despite diligent investigation by Plaintiffs into the cause of Plaintiff Danielle Baksic's injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the Plaintiff's Pelvic Mesh Device and Defendants' wrongful conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing of each Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

40. Any applicable statutes of limitation have been tolled by the knowing and active

concealment and denial of material facts known by the Defendants when it had a duty to disclose.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY – FAILURE TO WARN

41. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

42. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Device.

43. The Pelvic Mesh Device was expected to, and did, reach the intended consumers, handlers, and persons receiving the product, including Plaintiff Danielle Baksic, with no substantial change in the condition in which the products were designed, produced, manufactured, sold, distributed, labeled and marketed by Defendants.

44. The Pelvic Mesh Device was manufactured, designed, marketed, labeled and sold in a defective condition, for use by the Plaintiff Danielle Baksic's physician and/or healthcare provider and all other consumers of the product, making the products unreasonably dangerous.

45. The Pelvic Mesh Device implanted in Plaintiff Danielle Baksic was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide Plaintiff's implanting surgeon, Dr. Bruce Akright, sufficient or adequate warnings regarding, among other subjects:

a. The Pelvic Mesh Device's propensities to contract, retract, and/or shrink inside the body;

b. The Pelvic Mesh Device's propensities for degradation, fragmentation, disintegration and/or creep;

c. The Pelvic Mesh Device's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Pelvic Mesh Device;

f. The risk of chronic infections resulting from the Pelvic Mesh Device;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Device;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Device;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Device;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Device, including permanent nerve damage;

k. The hazards associated with the Pelvic Mesh Device;

l. The Pelvic Mesh Device's defects described herein;

m. Treatment of stress urinary incontinence and pelvic organ prolapse with the Pelvic Mesh Device is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence and pelvic organ prolapse with the Pelvic Mesh Device exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence and pelvic organ prolapse with the Pelvic Mesh Device makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Device puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Pelvic Mesh Device due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

r. Complete removal of the Pelvic Mesh Device may not be possible and may not result in complete resolution of the complications, including pain; and

s. The nature, magnitude and frequency of complications that could arise as a result of implantation of the Pelvic Mesh Device.

46. Defendants, by exercising reasonable diligence, could have made such warnings available to Plaintiff Danielle Baksic, Plaintiff's healthcare provider, and the medical community. But for these inadequacies, her doctor would have recommended different treatment or given Plaintiff counsel that would have led her to withhold consent.

47. As a direct and proximate result of Defendants' failure to provide Plaintiff, Plaintiff's healthcare provider, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare provider were not adequately informed of the potential dangers and/or defects of the Pelvic Mesh Device. Had Defendants properly disclosed the risks associated with the Pelvic Mesh Device for transvaginal use, Plaintiff would not have agreed to treatment with this device.

48. As a direct and proximate result of the wrongful acts and omissions of Defendants as set forth hereinabove, Plaintiffs suffered severe injuries, emotional distress, and economic damages.

49. WHEREFORE, Plaintiffs Danielle Baksic and Brian Baksic demand judgment against the Defendants, and requests compensatory damages for past, present, and future pain and

suffering, medical costs and expenses, lost wages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper and further, demands a trial by jury of all issues so triable.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

50. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

51. The Pelvic Mesh Device designed, marketed, manufactured and distributed by Defendants was defective and not reasonably safe due to its improper, inadequate, and defective design.

52. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Device. Plaintiff Danielle Baksic was an expected user or consumer of the Pelvic Mesh Device.

53. The Pelvic Mesh Device was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to the Pelvic Mesh Device implanted in Plaintiff were reasonably foreseeable to Defendants.

54. The Pelvic Mesh Device implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

55. The Pelvic Mesh Device implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

56. Plaintiff and her healthcare provider used the aforementioned Pelvic Mesh Device in a manner that was reasonably foreseeable to Defendants. Neither Plaintiff, nor her health care provider, could have, by the exercise of reasonable care, discovered the device's defective conditions or perceived its unreasonable dangers prior to the implantation of the Pelvic Mesh Device.

57. At the time of implantation of the Pelvic Mesh Device in Plaintiff Danielle Baksic, there were biologic materials, autologous grafts, allografts, and xenografts that would have been safer alternative devices to the Defendants' Pelvic Mesh Device. Additionally, there were larger pore lighter weight mesh devices that would have been safer alternatives.

58. The Pelvic Mesh Device implanted in Plaintiff Danielle Baksic was not reasonably safe for its intended uses and was defective as described herein with respect to its design. The Pelvic Mesh Device's design defects include, but are not limited to:

a. The use of polypropylene and/or collagen material in the Pelvic Mesh Device and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Pelvic Mesh Device to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Pelvic Mesh Device, including, but not limited to, the propensity of the Pelvic Mesh Device to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Pelvic Mesh Device, which,

when placed in the women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Pelvic Mesh Device for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Pelvic Mesh Device, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Pelvic Mesh Device for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals and/or human cadavers;

k. The harshness of collagen upon the female pelvic tissue, and the hardening of the Pelvic Mesh Device in the body;

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions; and

m. The failure to provide adequate instructions for use (IFU) and training.

59. As a direct and proximate result of the Pelvic Mesh Device's defective design, Plaintiffs suffered severe injuries, emotional distress, and economic damages.

WHEREFORE, Plaintiffs Danielle Baksic and Brian Baksic demand judgment against the Defendants, and request compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper and further, demands a trial by jury of all issues so triable.

COUNT III: NEGLIGENCE

60. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

61. For a Count of Negligence, it must be shown that Defendants had a duty to Plaintiffs, there was a breach of the duty, the breach was cause in fact and proximate cause of Plaintiffs' injuries, and a show of damages.

62. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of the Pelvic Mesh Device, including the duty to take all reasonable steps necessary to manufacture and sell products that were not defective or unreasonably dangerous to consumers and users of the product, including Plaintiffs herein. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Pelvic Mesh Device. Defendants breached their aforementioned duty by, among other things:

a. Failing to design the Pelvic Mesh Device so as to avoid an unreasonable

risk of harm to women in whom the Pelvic Mesh Device was implanted, including Plaintiff Danielle Baksic;

b. Failing to manufacture the Pelvic Mesh Device so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Device was implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Pelvic Mesh Device so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Device was implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Pelvic Mesh Device so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Device was implanted, including Plaintiff;

e. Failing to use reasonable care in the training and instruction to physicians for the safe use of the Pelvic Mesh Device;

f. Failing to use reasonable care in studying the Pelvic Mesh Device to evaluate its safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

g. By engaging in an aggressive doctor-directed marketing campaign to induce the use of their Pelvic Mesh Device, which misled doctors, including Plaintiff's treating physician, into believing that the dangers generally associated with Pelvic Mesh Device did not apply to Ethicon and J&J's product for various reasons.

63. The reasons that Defendants' negligence caused the Pelvic Mesh Device to be unreasonably dangerous and defective include, but are not limited to:

a. The use of polypropylene and/or collagen material in the Pelvic Mesh

Device and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Pelvic Mesh Device to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Pelvic Mesh Device, including, but not limited to, the propensity of the Pelvic Mesh Device to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms in the Pelvic Mesh Device, which, when placed in the women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Pelvic Mesh Device for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. The inelasticity of the Pelvic Mesh Device, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where it is implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Pelvic Mesh Device for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation

in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. The harshness of collagen upon the female pelvic tissue;

l. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions, and

m. The failure to provide adequate instructions for use (IFU) and training.

60. Defendants also negligently failed to warn or instruct Plaintiff and/or her health care provider of subjects including, but not limited to, the following:

a. The Pelvic Mesh Device's propensities to contract, retract, and/or shrink inside the body;

b. The Pelvic Mesh Device's propensities for degradation, fragmentation and/or creep;

c. The Pelvic Mesh Device's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Pelvic Mesh Device;

f. The risk of chronic infections resulting from the Pelvic Mesh Device;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Device;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Device;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Device;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Device including permanent nerve damage;

k. The hazards associated with the Pelvic Mesh Device;

l. The Pelvic Mesh Device's defects described herein;

m. Treatment of stress urinary incontinence with the Pelvic Mesh Device is no more effective than feasible, safer available alternatives;

n. Treatment of stress urinary incontinence with the Pelvic Mesh Device exposes patients to greater risk than feasible, safer available alternatives;

o. Treatment of stress urinary incontinence with the Pelvic Mesh Device makes future surgical repair more difficult than feasible, safer available alternatives;

p. Use of the Pelvic Mesh Device puts the patient at greater risk of requiring additional surgery than feasible, safer available alternatives;

q. Removal of the Pelvic Mesh Device due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

r. Complete removal of the Pelvic Mesh Device may not be possible and may not result in complete resolution of the complications, including pain; and

s. The nature, magnitude and frequency of complications that could arise as a result of implantation of the Pelvic Mesh Device.

64. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiffs suffered severe injuries, emotional distress, and economic damages.

WHEREFORE, Plaintiffs Danielle Baksic and Brian Baksic demand judgment against the

Defendants, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages, prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper and further, demands a trial by jury of all issues so triable.

COUNT IV: LOSS OF CONSORTIUM

65. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

66. Plaintiff Brian Backsic is the spouse of Plaintiff Danielle Baksic, and as a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff Brian Baksic has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

67. As a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff Brian Baksic has suffered the following injuries and damages:

a. Loss of household services sustained in the past;

b. Loss of household services that, in reasonable probability, Plaintiff Brian Baksic will sustain in the future;

c. Loss of consortium sustained in the past; and

d. Loss of consortium that, in reasonable probability, Plaintiff Brian Baksic will sustain in the future.

VICARIOUS LIABILITY

68. Whenever in this Petition it is alleged that Defendants did or omitted to do any act, it is' meant that Defendants' officers, agents, servants, employees, or representatives did

or omitted to do such act and that at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, or representatives.

69. As a direct and proximate result of Defendants' improper acts and/or omissions described herein, Plaintiffs were caused to suffer severe injuries and damages, including the following:

a. Physical pain and mental anguish sustained in the past;

b. Physical pain and mental anguish that, in reasonable probability, Plaintiffs will sustain in the future;

c. Disfigurement sustained in the past;

d. Disfigurement that, in reasonable probability, Plaintiffs will sustain in the future;

e. Loss of earning capacity sustained in the past;

f. Loss of earning capacity that, in reasonable probability, Plaintiffs will sustain in the future;

g. Physical impairment sustained in the past;

h. Physical impairment that, in reasonable probability, Plaintiffs will sustain in the future;

i. Medical care expenses incurred in the past; and

j. Medical care expenses that, in reasonable probability, Plaintiffs will incur in the future.

EXEMPLARY DAMAGES

70. Defendants' conduct described herein, when viewed objectively from the

standpoint of Defendants at the time of the occurrence, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Moreover, Defendants had actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, and welfare of others. Thus, Plaintiffs seek exemplary damages in an amount to be determined by the jury.

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

71. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

72. Despite diligent investigation by Plaintiffs into the cause of Plaintiff Danielle Baksic's injuries, including consultations with Plaintiff's medical provider, the nature of Plaintiff's injuries and damages and their relationship to the Pelvic Mesh Product were not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

73. The running of the statute of limitations in this cause is tolled during anytime in which Plaintiffs suffered under a legal disability.

74. Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed from Plaintiffs the nature of Plaintiff Danielle Baksic' injury and the connection between the injury and Defendants' tortious conduct. Defendants had actual knowledge of the wrong, they concealed the wrong by making a misrepresentation or by remaining silent when they had a duty to speak, they had a fixed

purpose to conceal the wrong, and Plaintiff Danielle Baksic and her physician reasonably relied on the misrepresentation or silence.

JURY TRIAL DEMAND

75. Plaintiffs hereby respectfully request a trial by jury and submit the appropriate fee herewith.

PRAYER

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray that Defendants be cited to appear and answer herein, and that upon final hearing hereof, Plaintiffs have judgment against Defendants for all damages to which they are entitled under the laws of the State of Texas, which amount exceeds the minimum jurisdictional limits of this Court; for pre-judgment interest in accordance with law and/or at the highest legal rate; for interest on the judgment; for costs of suit; for exemplary damages; and for such other and further relief, either at law or in equity, to which Plaintiffs have shown or will show themselves justly entitled.

Respectfully Submitted,

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